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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,792	12/22/2000	Donald C. Foster	99-107	1664

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,792

Applicant(s)

FOSTER ET AL.

Examiner

Fozia M Hamud

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04/29/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction:

1. Applicant's election of the polypeptide of SEQ ID NO:12 as the fIL-20RA subunit and the polypeptide of SE ID NO:15 as the IL-20RB subunit in the reply filed on 22 December 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 8-12 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions. Claims 8-12 do not recite the elected SEQ ID Nos for the first and the second subunits of IL-20 R.

Claim objections:

2a. Claim 1 is objected to because of the following informalities:

Claim 1 is objected to because it recites non-elected SEQ ID Nos.

Appropriate correction is required.

Specification:

3a. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification:

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim rejections-35 USC § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for an isolated IL-20 receptor heterodimer, comprising the full length amino acid sequence of the IL-20 R alpha subunit and the full length amino acid sequence of the IL-20R beta subunit, does not reasonably provide enablement for isolated soluble receptor comprising the polypeptide of SEQ ID NO:12 and the polypeptide of SEQ ID NO:15, or said heterodimer which is fused to a II or a portion of an immunoglobulin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims 1-7 are drawn to an isolated soluble receptor that comprises an IL-20RA subunit and an IL-20RB subunit, said subunits which comprise of the amino acid sequence of SEQ ID NO: 12 and 15, respectively. The polypeptide of SEQ ID NO:12 is comprised of 221 amino acid residues and the instant specification describes it as being the extracellular domain of the IL-2-0A receptor, (page 7, lines 3-4). The polypeptide of SEQ ID NO:15 is comprised of 203 amino acid residues and the instant specification describes it as being the extracellular domain of the IL-20B receptor, (page 7, lines 8-10). The art recognizes that IL-20 receptor is a class II cytokine receptor which consists of IL-20R alpha and IL-20R beta subunits, and that both subunits are needed for IL-20 binding and activation, (Blumerg et al Cell, Vol.104, pages 9-19, 2001, especially page 12, and page 15, column 2). Blumerg et al also teach that both IL-20 ligand and IL-20 receptor subunits are expressed in psoriasis (page 15, column 2). The

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instant specification discloses that IL-20 binds to the IL-20A and IL-20 B heterodimer and that it stimulates the proliferation of cells that are transfected with both of the IL-20 receptor subunits, (Examples 7 and 8). However, the instant specification does not disclose that IL-20 binds to and activates a soluble receptor comprising only the IL-20A and IL-20B extracellular domains. The specification discloses how to make a heterodimer comprising the IL-20 receptor subunits (full length) and immunoglobulin, however, it fails to disclose whether said heterodimer is functional. Furthermore, the instant specification does not disclose how to make the soluble receptor of claim 1. Although the figures of the instant invention disclose drawings of the claimed receptor, the specification does not teach how to link the two subunits of the claimed receptor. The criteria set forth in *Ex parte Forman* (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue experimentation. In the instant case, the biology of receptor/ ligand interaction is very complex and IL-20 receptor is unique in that both of the subunits are required for IL-20 binding. Therefore, one of ordinary skill in the art would not be able to predict whether a soluble receptor comprising only the IL-20A and IL-20B extracellular domains would be functional. Furthermore, even if Applicants demonstrate that the claimed heterodimer is able to bind to IL-20, one of ordinary skill in

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the art would not know whether said heterodimer would function as an agonist or as an antagonist. Although many soluble receptors compete with the membrane bound receptors for the ligand, and therefore display inhibitory effect, some soluble receptors have agonistic effect. For example Rose et al, (Acta Biochimica Polonica, Vol. 50, No.3, pages 603-611, 2003, abstract) teach that while most soluble receptors are antagonists, soluble receptors of the IL-6 family are agonists. Therefore, due to the lack of direction/guidance presented in the specification regarding whether the claimed soluble receptor would retain the desired activity, the complex nature of the invention, the state of the prior art establishing that IL-20 is unique in that both of the subunits are required for IL-20 binding and activation and that soluble receptors can be either agonists or antagonists, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claim rejections-35 USC § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claim 5 recites ".....at least one cysteine residue....", which renders the claim indefinite because it is not clear how many cysteine residues should the claimed receptor comprise, 1, 2, 5 or more. The metes and bounds of the claim cannot be ascertained. Appropriate correction is required.

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4b. claim 6 recites "...subunit is fused to all or a portion of the constant regions...", which renders the claim indefinite, because it unclear which portion to of the constant region of immunoglobulin should the subunits be fused to. Appropriate correction is required.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, insofar as it depends from claim 6 for the limitations set forth directly above.

Conclusion:

5. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
23 September 2004


JANET ANDRES
PRIMARY EXAMINER